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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,674	02/15/2001	Karen W. Shannon	10971464-3	3167

22878 7590 12/02/2002

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EXAMINER

MAHATAN, CHANNING

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 12/02/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,674

Applicant(s)

SHANNON ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) 41-97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 and 98-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-101 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 9 Sheets 6) ☐ Other:

DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election of Group I (claims 1-40 and 98-101; drawn to methods of predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence utilizing a predetermined number of unique oligonucleotides within a nucleotide sequence) is acknowledged. In view of applicants' arguments regarding the species election requirement as set forth and upon further review of the claims and specification the examiner is vacating all species elections. Therefore, all claims in Group I are under examination. Claims 41-97 are withdrawn from examination as not directed to the elected invention.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-40, and 98-101.

Obviousness-Type Double Patenting

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q. 2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); and, *In re Thorington*, 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

Claims 1-40, 98, and 99 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40, 97, and 98 of U.S. Patent No. 6,251,588. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims define an invention which is a method for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence with such similarity making the inventions have overlapping embodiments. Step (a) of claims 1 and 97 in U.S. Patent No. 6,251,588 limits the claim language to "unique oligonucleotides of at least 5 nucleotides in length within a nucleotide sequence of at least 30 nucleotides in length that is hybridizable with said target nucleotide sequence", while step (a) of claims 1 and 98 in the instant application limits the claim language to "unique oligonucleotides within a nucleotide sequence that is hybridizable with said target nucleotide sequence. The claims of the instant application are broadly applicable to the specified nucleotide lengths of U.S. Patent No. 6,251,588 and thus are obvious.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-40 and 98-101 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 1, 98, 100, and all claims dependent therefrom are unclear in regards to the preamble and remainder of the claim. Applicants' claim "a method for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence", however, the final step indicates a step of selecting a hybridization oligonucleotide. It is noted that step (b) determines and evaluates the predictive ability of each oligonucleotide to hybridize to said target nucleotide. Applicants' can resolve this issue by particularly pointing whether the method claimed is directed 1) a method for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence or 2) selecting a hybridization oligonucleotide. Clarification is required, for the claim is vague and indefinite.

Claims 1 (line 3), 3 (line 1), 4 (line 1), 24 (line 3), 25 (line 3), 38 (line 2), 98 (lines 4 and 13), and 100 (line 6) recite the term "unique" which is vague and indefinite. It is unclear what applicants' are referring to/require as "unique". Applicants can resolve this issue by particularly pointing out what is referring to or required to be "unique". Clarification of the metes and bounds, via clearer claim language, is required.

Claim 10 (line 2) recites the term "factor" which is vague and indefinite. It is unclear the "factor" applicants are referring to derive said parameter. Applicants can resolve this issue by particularly pointing out what the factor is, via clearer claim language.

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Claim 28 (lines 2-3) and all claims dependent therefrom recite the phrase "poorly correlated" which implies some degree of correlation. Applications can resolve this issue by particularly pointing out the range/ criteria of what is considered to be "poorly correlated". Clarification of the metes and bounds, via clearer claim language, is required.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-10, 15, 17-22, 98, and 100 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Hyndman et al.

Hyndman et al. describes a computer program which simulates actual hybridization experiments between probes (RNA and DNA) and sequences (RNA and DNA) in a database through the creation of a set of candidate oligonucleotides from a target gene, wherein each candidate oligonucleotide is searched for in a large sequence database for sequences that will hybridize to the oligonucleotide (instant claims 1, 17, 18, 20, 21, 98, and 100; Abstract; page 1091, column 1, lines 28-31; and Figure 2). The program calculates the melting temperature or free energy of all sequences in a database (instant claims 5-10 and 15; Abstract and page 1091, columns 1-2, lines 34-37 and 1-2, respectively). The user is able to specify salt concentration, oligonucleotide concentration, and the desired melting temperature (page 1094, column 1, lines 4-5). A probe set is created (capable of being edited; i.e. the complement or a tag sequence (chemically modified nucleotide) can be added), containing all possible oligonucleotides derived from the target sequence which fits a chosen specification, such as specified length (interpreted

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to include probes of identical length), melting temperature, or free energy of hybridization (instant claims 2, 3, 19, and 22; page 1091, column 2, lines 13-28). The computer hybridization simulation determines the specificity of each sequence to which a particular probe may hybridize (i.e. binding strength) then selects the most favorable/stable probes (pages 1091-1092, columns 2-1, lines 29-37 and 11-10, respectively). Data generated by the computer hybridization simulation can be exported to a spreadsheet format with various information: melting temperature, number of hybridizable and cross-hybridizable sequences, difference in melting temperature or entropy of the probe, length of the oligonucleotides, GC content, terminal GC content (page 1093, columns 1-2, lines 5-26 and 1-22). A particular application of the describes program is to identify a probe that identifies all known types of a particular gene family by selecting common probes to all targets of interest, wherein a sub-set of possible probes are identified and the user selects the probe (i.e. common or consensus probes) (pages 1094, column 1, lines 20-39). Thus, Hyndman et al. clearly anticipates the claimed invention.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

Examiner Initials:

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
AL 1631